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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,307	10/16/2001	Ganapati R. Mauze	10003714	7843

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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,307

Applicant(s)

MAUZE ET AL.

Examiner

Jeffrey Fredman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-8 and 14-20 in the paper filed July 11, 2003 is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed October 16, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Interpretation

The current claims are drawn to "cartridges" which comprise one of a variety of systems, without any structural elements present in the claim. A careful review of the specification finds that the specification itself lacks any structural limitations on the claimed "cartridges". However, because the claim does not use the "means plus function" format, the claim will not be deemed indefinite as per *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376, 58 USPQ2d 1801, 1806 (Fed. Cir. 2001), but rather will be interpreted broadly to include any component which can achieve the claimed function whatsoever.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8 and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (U.S. Patent 5,856,174).

Lipshutz teaches a “cartridge” (see figure 3 and column 2, lines 15-43) and an analytical instrument (see figure 3) which comprises a fluid transport system (column 2, line 23), a hybridization reaction chamber (see column 2, lines 26-28), or an amplification chamber used for PCR amplification (see column 2, lines 48-53 and column 6, lines 28-67). Lipshutz teaches that the “cartridge” may be connected to a sensing “cartridge” either directly or indirectly (see column 11, lines 48-52).

With regard to claim 2, Lipshutz teaches the use of a fluid interface such as capillary electrophoresis for detection (see column 12) as well as by a mechanical/electrical interface into a reader device (column 13, lines 25-35).

With regard to claims 3 and 7, Lipshutz teaches fluid transport to remove unwanted materials (see column 6, lines 3-27, for example).

With regard to claims 4, 15, Lipshutz teaches DNA testing (see column 6, lines 28-67).

With regard to claims 5, 18, Lipshutz teaches thermocycling to perform PCR (see column 6, lines 28-67).

With regard to claim 6, Lipshutz teaches fluid systems which transport fluid to some chambers thereby increasing their volume (see column 2, lines 15-43).

With regard to claim 8, Lipshutz teaches fluid transport of DNA to a hybridization array, so the fluid is not mixed with the bound oligonucleotide probes (see column 2, lines 15-43).

With regard to claims 16 and 17, Lipshutz teaches cell lysis and DNA extraction (see column 5, lines 15-20, where Lipshutz discusses extraction of nucleic acids from whole cells).

With regard to claims 19 and 20, Lipshutz teaches a removable cartridge (see column 26, line 43 to column 28, line 24), where the cartridge is in fluid contact with the base (see column 18, lines 43-49, for example).

5. Claims 1-8, 14-17, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakata et al (U.S. Patent 5,296,378).

With regard to Sakata, the flow cytometer column is interpreted as the "companion cartridge" while the laser detection and photomultiplier tube are interpreted as the "sensing cartridge".

Sakata teaches a "cartridge" (see figure 1 and column 12, line 20, where a Sakata teaches a flow cell 14 which is a "companion cartridge" that permits fluid flow) which is directly connected mechanically and electrically to a "sensing cartridge" (see figure 1 and column 12, lines 21-39, where the optics detect the sample using a photomultiplier tube). Sakata also teaches an "analytical instrument comprising the cartridges (see figure 1).

With regard to claims 2, 3 and 7, Sakata teaches a flow cell which permits fluid transport between regions (see figure 1 and column 12, lines 1-39).

With regard to claims 4, 6, 8, 15, Sakata teaches flowing a carrier fluid which permits a hematology assay to be performed and which adds liquid to the flow cell (see 11, lines 38-50, column 12, lines 1-39).

With regard to claim 5, Sakata teaches "incubation" of the sample as it flows through the flow cell 14 (see column 12, lines 1-39).

With regard to claim 16, Sakata teaches lysis of a cell (see column 12, lines 55-62, where erythrocytes are selectively lysed).

With regard to claim 17, the lysis of the cells inherently causes DNA to be isolated from the mitochondria (see column 12, lines 55-62).

With regard to claims 18 and 19, the flow cell can be removed from the flow cytometer, inherently and the flow cytometer has a carrier fluid system (see figure 1).

6. Claims 1-8, 14, 15 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Andresen et al (U.S. Patent 6,126,804).

Andresen teaches a "cartridge" (see figures 1 and 2) and an analytical instrument (see figures 1 and 2) which comprises a PCR reaction wells linked to capillary electrophoresis columns (see columns 3 and 4). Andresen teaches attachment of the column to a sensor which detects the amplified DNA (see column 4, lines 1-8).

With regard to claim 2, Andresen teaches the use of a fluid interface such as capillary electrophoresis for detection (see column 4) as well as by a

mechanical/electrical interface into a reader device (see figure 5 and column 5, lines 17-25).

With regard to claims 3 and 7, Andresen teaches a flow cell which permits fluid transport between regions (see figures 1 and 2).

With regard to claims 4, 15, Andresen teaches DNA testing (see column 5, lines 1-30).

With regard to claims 5, 18, Andresen teaches thermocycling to perform PCR (see column 3, lines 55-65).

With regard to claim 6, Andresen teaches fluid systems which transport fluid to some chambers thereby increasing their volume (see figure 1).

With regard to claim 8, Andresen teaches fluid transport of DNA in a capillary electrophoresis column, so the fluid is a "carrier" for the amplified product (see column 5, lines 1-40).

With regard to claims 19 and 20, Andresen teaches a removable cartridge (see figure 1), where the cartridge is in mechanical contact with the detection device (see figures 1, 2 and 5).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1634